SEP 14 2005

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510(K) Summary

Submitter:	Cynosure, Inc. 10 Elizabeth Drive Chelmsford, MA 01824
Contact:	George Cho Senior Vice President of Medical Technology
Date Summary Prepared:	February 14, 2005
Device Trade Name:	Affinity QS Q-Switched Nd:YAG Laser system
Common Name:	Q-Switched Nd:YAG laser
Classification Name:	Instrument, surgical, powered, laser 79-GEX 21 CFR 878.48
Equivalent Device:	Medlite C6 Q-Switched Nd:YAG Laser system
Device Description:	The Affinity QS Q-Switched Nd:YAG Laser is a Q-Switched, frequency doubled laser system. It provides both 1064nm and 532nm wavelengths. Laser emission activation is by foot switch. Overall weight of the laser is 180 lbs., and the size is 25" x 15" x 78" (LxWxH). Electrical requirement is 230 VAC, 20A, 50-60 Hz, single phase.
Intended Use:	The Affinity QS laser is intended for treatment of vascular lesions, pigmented lesions, and for hair, tattoo removal, and the incision, excision, ablation, vaporization of soft tissue for general dermatology.
Comparison:	The Affinity QS laser system has identical indication for use, the same principle of operation, and essentially the same wavelength range and pulse energy range as the predicate device.
Nonclinical Performance Data:	none
Clinical Performance Data:	none
Conclusion:	The Affinity QS laser is a safe and effective device for the treatment of vascular and pigmented lesions, for hair and tattoo removal, and for the incision, excision, ablation, vaporization of soft tissue for general dermatology.
Additional Information:	none

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 14 2005

Mr. George Cho
Senior Vice President
Medical Technoogy
Cynosure Incorporated
10 Elizabeth Drive
Chelmsford, Massachusetts 01824

Re: K050382
Trade/Device Name: Cynosure Affinity QS Laser
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: August 31, 2005
Received: September 2, 2005

Dear Mr.Cho:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K050382

Device Name: Cynosure Affinity QS Laser

Indications For Use:

The Affinity QS Laser is intended for the treatment of vascular lesions, pigmented lesions, and for hair removal, tattoo removal, and the incision, excision, ablation, vaporization of soft tissue for general dermatology.

Prescriptive Use___X___ OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Re... and Neurological Devices

510(k) Number K050382

Prescription Use___X___ OR Over-The-Counter Use_____

(Optional Format 1-2-96)